REMARKS/ARGUMENTS

The Examiner is thanked for the thorough explanation of the most recent ground of rejection. The claim amendments herein are believed to address the Examiner's concerns.

Claims 1 and 13-16 stand rejected by the Examiner as allegedly anticipated by Simard et al. The Examiner explains in the later "Response to Arguments" section that the Examiner does not view the preamble language as affirmatively limiting the scope of the claims, both because it is in the preamble and because it is allegedly simply a statement of intended use. However, the Court of Appeals has ruled that where, as here, applicant relies upon the preamble to distinguish prior art, or where the preamble is "necessary to give life, meaning and vitality to the claims" the preamble does act as an affirmative limitation on the claim scope. See, *On Demand Machine v. Ingram Industries*, 442 F.3d 1331, 1343 (Fed. Cir. 2006). Nonetheless, to advance the prosecution, applicant has moved the language in question from the preamble to the end of claim 1 where it now appears as an affirmative limitation. Additionally, it is not merely a statement of intended use, but now includes the additional limitation "pharmaceutical dosage form" which is a structural limitation with well-known meaning in the pharmaceutical industry such as tablets, capsules and the like. See also pages 31-36 of the specification for other examples.

To sustain a rejection under 35 U.S.C. § 102, the Examiner must show that each and every limitation of the claims is met by a single reference. *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). There must be no difference between the claimed invention and the reference disclosure. *Ibid.* Among the limitations of the rejected claims that are neither disclosed nor suggested by these references is the limitation requiring "a pharmaceutical dosage form". This is an affirmative structural limitation to the product claim which is neither disclosed nor suggested by the cited Simard reference. In Simard, the active agents are added to cell culture (a mixture of cancer cells and media for growing them). The result is not a "pharmaceutical dosage form." Accordingly, it is urged that the rejection under 35 U.S.C. §102 over Simard should be withdrawn.

Claims 1-2 and 13-16 stand rejected by the Examiner under 35 U.S.C. §102 as allegedly anticipated by Couillard. To sustain this rejection, all claim limitations must be present in the single

Couillard reference. See, *Scripps*, *supra*. In Couillard, various active agents are administered to laboratory animals. The result, of course, is laboratory animals with such active agents in the blood and/or tissues of that animal. There is no "pharmaceutical dosage form" as required by the claims. Accordingly, it is urged that the rejection under 35 U.S.C. §102 over Couillard should be withdrawn.

Claims 17-19, 22-23 and 35-41 stand rejected as allegedly obvious under 35 U.S.C. §103 over the combination of Simard and Couillard. However, combining Simard and Couillard would not result in a "pharmaceutical dosage form" as presently claimed. As noted above, Simard teaches cells in culture and Couillard teaches laboratory animals. It is difficult to imagine what would result if one combined cancer cell cultures with laboratory animals, but it certainly would not be a "pharmaceutical dosage form."

Nor would it be obvious to selectively remove estrogen and SERM from these prior art references and recombine them into a pharmaceutical dosage form having both agents. The references themselves teach against the use of estrogen. All claims require "estrogen" while both the Simard reference and the Couillard reference teach against estrogen. Couillard notes (at abstract lines 6-7) that "Estrone caused a 10-fold increase in ZR-75-1 tumor area . . ." ZR-75-1 is defined as human mammary tumor. Likewise, Simard states that "estrogens play a predominant role in the development and growth of human breast cancer . . ." (Abstract, lines 1-2). On page 9 of the Office Action, the Examiner responds to applicant's prior arguments regarding the fact that Simard and Couillard teach against estrogen by stating that these arguments are not germane to a rejection based on anticipation. However, applicant did not make these arguments in connection with the anticipation rejection. Instead, applicant specifically makes this "teaching away" argument in connection with the obviousness rejection over the combination of Simard and Couillard under 35 U.S.C. §103. In the context of obviousness, this "teaching away" is both relevant (See MPEP 2144.08) and conclusive that the invention is not obvious. The claims rejected for obviousness over Simard and Cuillard are distinguishable by their requirement of "estrogen," which Simard and Cuillard teach should be avoided. While the Examiner is correct that such "teaching away" is not relevant to the above anticipation rejection, "teaching away" is of critical importance on the issue of obviousness. Thus, the rejection under 35 U.S.C. §103 over the combination of Simard and Couillard should be withdrawn

Finally, claims 1-2, 13-19, 22-23 and 35-41 stand rejected as allegedly obvious over Luo, Barrett-Conner and Do Nascimento in view of Labrie WO 96/26201. However, Luo does not disclose an estrogen, Barrett-Conner does not test the presently-claimed SERMs on cholesterol, the Do Nascimento abstract expressly states that "[s]erum cholesterol levels were not altered by any of the treatments." Accordingly it is urged that there is no reason in these references to combine an estrogen with the SERM recited in the present claims. This deficiency of the prior art is not overcome by the cited Labrie reference which merely discusses certain antiestrogenic properties of the disclosed compounds. It is not seen how this discussion would motivate one of skill in the art to combine the disclosed compounds with the estrogens of either Do Nascimento or Barrett-Conner. Accordingly, it is urged that the obviousness rejection over Luo, Barrett-Conner, Do Nascimento and Labrie WO 96/26201 should be withdrawn.

It is urged that the application is now in condition for allowance. Issuance of a notice of allowance is solicited.

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